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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,368	02/07/2002	Alice C. Martino	C-3527/I/US	2557

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EXAMINER	
HUI, SAN MING R	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,368	MARTINO ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,7-9,23-25 and 32-42* is/are pending in the application.

4a) Of the above claim(s) *39-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 7-9, 23-25, and 32-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed August 22, 2005 have been entered. The cancellation of claims 1-4, 6, and 16-22 is acknowledged. Claims 5, 7-9, 23-25, and 32-42 are pending.

Claims 39-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 10, 2005.

The outstanding rejections under 35 USC 112 are withdrawn in view of the amendments filed August 22, 2005.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 7-9, 23-25, and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,273,975 ('975) in view US Patent 5,565,466 ('466).

'975 teaches the herein claimed compounds as useful in stimulating sexual activity and treating sexual dysfunction (See col. 2, lines 19-23). '975 also teaches the effective dosage as 10mg orally in multiple doses (See col. 9, lines 58-61). Various routes of administration were taught in '975 including oral, parenteral, rectal (See col. 9, line 66 – col. 10, line 5).

'975 does not expressly tech the herein claimed pharmaceutical dosage forms. '975 does not expressly teach the dosage as 0.1 to 5 mg.

'466 teaches a buccal composition comprising a vasodilator for modulating the sexual response in human. '466 the buccal dosage form can be formulated into sublingual tablets, lozenge, chewing gums, and oral strips and films (See col. 7, lines 29-49). '466 teaches useful vasodilators include nitroglycerin and nicotinyl alcohol(See claim 2).

It would have been obvious to one of ordinary skill in the art at the time of invention to formulate the compounds of '975 into the herein claimed dosage forms. It would have been obvious to one of ordinary skill in the art at the time of invention to formulate the herein claimed dosage.

One of ordinary skill in the art would have been motivated to formulate the compounds of '975 into the herein claimed dosage forms and the herein claimed dosage. Firstly, the skilled of artisan would possess all conventional administration method of the active compounds such as sublingual tablets, lozenge, chewing gums,

oral strips and films. The selection of one or another well-known conventional dosage forms would be seen as a simple selection from among obvious alternatives. Furthermore, the optimization of result effect parameters (e.g., dosage range) is obvious as being within the skill of the artisan since the compounds of '975 is effective in 10mg daily in multiple times. Therefore, adjusting the dosage to less than 10mg per dose, e.g., 2.5mg per tablet four times daily, would be obvious.

Claims 5, 7-9, 23-25, 32, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over '975 in view of US Patent 5,501,861 ('861).

'975 teaches the compounds recited in claims 5, 8, and 23 as useful in treating anxiety (See the abstract). '975 also teaches the effective dosage as 10mg orally in multiple doses (See col. 9, lines 58-61).

'975 does not expressly teach the compounds as formulated into a fast-melt formulation. '975 does not expressly teach the dosage as 0.1 to 5 mg.

'861 teaches a fast-melt formulation for antianxiety and antidepressants compounds which also provide advantages for providing an easy dosage forms for elderly to ingest (See col. 3, lines 37-38).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the antianxiety and antidepressant compounds of '975, in the herein claimed dosage, into fast-melt formulation of '861.

One of ordinary skill in the art would have been motivated to formulate the antianxiety and antidepressant compounds of '975, in the herein claimed dosage, into

fast-melt formulation of '861 since formulate antidepressant and antianxiety compounds of '975 would provide an advantage of fast-melt formulation that is easily ingested for elderly patients. Furthermore, the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan since the compounds of '975 is effective in 10mg daily in multiple times. Therefore, adjusting the dosage to less than 10mg per dose, e.g., 2.5mg per tablet four times daily, would be obvious.

Response to Arguments

Applicant's arguments filed August 22, 2005 averring the cited prior arts' failure to teach the herein claimed dosage have been fully considered but they are not persuasive. Examiner notes that '975 teaches the effective amount of compounds of '975 as 10mg daily in multiple times. Therefore, adjusting the dosage to less than 10mg per dose, e.g., 2.5mg per tablet four times daily, would be obvious.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Primary Examiner
Art Unit 1617